

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO																															
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>																															
(Use as many sheets as necessary)																															
Sheet 1 of 4 Attorney Docket No: 41577/317929																															
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2"></th> <th colspan="2" style="text-align: center;"><i>Complete if Known</i></th> </tr> <tr> <th colspan="2"><b>Application Number</b></th> <td colspan="2">10/542,449</td> </tr> <tr> <th colspan="2"><b>Filing Date</b></th> <td colspan="2">December 13, 2005</td> </tr> <tr> <th colspan="2"><b>First Named Inventor</b></th> <td colspan="2">James Edward Eyles</td> </tr> <tr> <th colspan="2"><b>Art Unit</b></th> <td colspan="2">1645</td> </tr> <tr> <th colspan="2"><b>Examiner Name</b></th> <td colspan="2">Swartz, Rodney P.</td> </tr> </thead> <tbody> <tr> <td colspan="4" style="height: 40px;"></td> </tr> </tbody> </table>						<i>Complete if Known</i>		<b>Application Number</b>		10/542,449		<b>Filing Date</b>		December 13, 2005		<b>First Named Inventor</b>		James Edward Eyles		<b>Art Unit</b>		1645		<b>Examiner Name</b>		Swartz, Rodney P.					
		<i>Complete if Known</i>																													
<b>Application Number</b>		10/542,449																													
<b>Filing Date</b>		December 13, 2005																													
<b>First Named Inventor</b>		James Edward Eyles																													
<b>Art Unit</b>		1645																													
<b>Examiner Name</b>		Swartz, Rodney P.																													

<b>US PATENT DOCUMENTS</b>					
Examiner Initial *	Cite No	Document Number Number-Kind Code	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-5,126,147	06-30-1992	Silvestri, et al.	
		US-5,643,605	07-01-1997	Cleland, et al.	
		US-5,585,106	12-17-96	Gristina, et al.	
		US-5,279,936	01-18-1994	Vorpahl	
		US-2005/0181063	08-18-2005	Alpar, et al.	
		US-2006/0239931	10-26-2006	Eyles, et al.	
		US-2008/0131377	06-05-2008	Eyles, et al.	
		US-2008/0057083A1	06-03-2008	Alpar, et al.	
		US-5,985,285	11-16-1999	Titball, et al.	
		US-2003/0171258A1	09-11-2003	Alpar et al.	

<b>FOREIGN PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No	Foreign Patent Document Country Code Number Kind Code	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		WO 92/17165	10-15-1992	CSL Limited	
		WO 94/15636	07-21-1994	CSL Limited	
		WO-92/05791A1	04-1992	Ruprecht, et al.	
		WO 99/57176A1	11-1999	Amsden, et al.	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO																															
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>																															
(Use as many sheets as necessary)																															
Sheet 2 of 4 Attorney Docket No: 41577/317929																															
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="4" style="text-align: center; padding-bottom: 5px;"><i>Complete if Known</i></th> </tr> <tr> <th style="width: 25%;">Application Number</th> <td colspan="3">10/542,449</td> </tr> <tr> <th>Filing Date</th> <td colspan="3">December 13, 2005</td> </tr> <tr> <th>First Named Inventor</th> <td colspan="3">James Edward Eyles</td> </tr> <tr> <th>Art Unit</th> <td colspan="3">1645</td> </tr> <tr> <th>Examiner Name</th> <td colspan="3">Swartz, Rodney P.</td> </tr> </thead> <tbody> <tr> <td colspan="4" style="height: 40px;"></td> </tr> </tbody> </table>				<i>Complete if Known</i>				Application Number	10/542,449			Filing Date	December 13, 2005			First Named Inventor	James Edward Eyles			Art Unit	1645			Examiner Name	Swartz, Rodney P.						
<i>Complete if Known</i>																															
Application Number	10/542,449																														
Filing Date	December 13, 2005																														
First Named Inventor	James Edward Eyles																														
Art Unit	1645																														
Examiner Name	Swartz, Rodney P.																														

	WO 94/20070	03-06-2008	Duncan, et al.	
	WO 99/01498	01-14-1999	Davis, et al.	
	WO 97/20576	06-12-1997	Illum	
	WO 98/30207	07-16-1998	Bassett, et al.	
	WO 96/05810	02-29-1996	Bassett, et al.	
	EP 0571671	12-01-1993	The Procter and Gamble Company	
	WO 96/10421	04-11-1996	Chatfield	

<b>OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		ALONSO, M., et al., "Biodegradable Microspheres as Controlled-Release Tetanus Toxoid Delivery Systems," <i>Vaccine</i> , 1994 Vol. 12 No. 4, pp. 299-306.	
		BRANDTZAEG, P., "Immune Functions of Human Nasal Mucosa and Tonsils in Health and Disease," <i>Immunology of the Lung and Upper Respiratory Tract</i> , (ed. Bienenstock J.). McGraw-Hill, New York, 1984, pp. 28-95.	
		EYLES, J., et al., "Immune Responses to Mucosally Administered Co-encapsulated <i>Yersinia Pestis</i> Antigens," <i>I.J. Pharm. Pharmacol.</i> , 1997 Vol. 49, Suppl. 4, p. 85.	
		EYLES, J., et al., "Generation of Protective Immune Responses to Plague by Mucosal Administration of Microsphere Co-encapsulated Recombinant Subunits," <i>Journal of Controlled Release</i> , 2000, Vol. 63 pp. 191-200.	
		EYLES, J., et al., "Protection from Pneumonic Plague Following Intra-Nasal Immunisation with Microencapsulated Y. Pestis Antigens: A Dose Response Study," <i>Vaccines</i> , 2-5 December 1997, 14.23.	
		EYLES, J., et al., "Intranasal administration of poly-lactic acid microspheres co-encapsulated <i>Yersinia pestis</i> subunits confers protection from pneumonic plague in the mouse," <i>Vaccine</i> , 1998, Vol. 16, No. 7, pp. 698-707	
		ELDRIDGE, J., et al., "New Advances in Vaccine Delivery Systems," <i>Seminars in Hematology</i> , 1993, Vol. 30, No. 4, Suppl. 4 (October), pp 16-25.	
		ELVIN, S.J., et al., "Protection against Bubonic and Pneumonic Plague with a Single Dose Microencapsulated Sub-Unit Vaccine," 2006, Vol., 24, pp. 4433-4439	
		HILBERT, A., et al., "Biodegradable Microspheres Containing Influenza A Vaccine: Immune Response in Mice," <i>Vaccine</i> , 1999, Vol. 17, pp. 1065-1073.	

---

**EXAMINER**

---

**DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.<sup>1</sup> Applicant's unique citation designation number (optional) <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>			
<i>Complete if Known</i>			
<b>Application Number</b>		10/542,449	
<b>Filing Date</b>		December 13, 2005	
<b>First Named Inventor</b>		James Edward Eyles	
<b>Art Unit</b>		1645	
<b>Examiner Name</b>		Swartz, Rodney P.	
Sheet	3	of	4
Attorney Docket No: 41577/317929			

	FLICK-SMITH, H. C., et al., "Mucosal or Parenteral Administration of Microsphere-Associated Bacillus anthracis Protective Antigen Protects against Anthrax Infection in Mice," 2002, Vol. 70, pp. 2022-2028	
	JENKINS, P., et al., "Aspects of the Design and Delivery of Microparticles for Vaccine Applications," <i>Journal of Drug Targeting</i> , 1995, Vol. 3, pp. 79-81.	
	KOTZE, A. et al.; "Enhancement of Paracellular Drug Transport with Highly Quaternized N-Triethyl Chitosan Chloride in Neutral Environments: In Vitro Evaluation in Intestinal Epithelial Cells (Caco-2)," 1999, <i>Journal of Pharmaceutical Sciences</i> ; Vol. 88, No. 2, pp. 253-257	
	KOTZE et al; "N-trimethyl Chitosan chloride as a potential absorption enhancer across mucosal surfaces: in vitro evaluation in intestinal epithelial cells (Caco-2); <i>Pharmaceutical Research</i> ; Vol. pp. 1997 1197-1202	
	LEARY, E., et al. "Active Immunization with Recombinant V Antigen From <i>Yersinia pestis</i> Protects Mice Against Plague," <i>Infection and Immunity</i> , 1995, Vol. 63, No. 8, pp. 2854-2858.	
	MORRIS, W., et al., "Potential of Polymer Microencapsulation Technology for Vaccine Innovation," <i>vaccine</i> , 1994, Vol. 12, No. 1, pp. 5-11.	
	OGAWA, Y., et al., "A New Technique to Efficiently Entrap Leuprolide Acetate into Microcapsules of Polylactic Acid or Copoly (Lactic/Glycolic) Acid," <i>Chem. Pharm. Bull.</i> , 1988, Vol. 36 No. 3, pp. 1095-1103.	
	O'HAGAN, D., et al., "Microparticles as Potentially Orally Active Immunological Adjuvants," <i>Vaccines</i> , 1989, Vol. 7, pp. 421-424.	
	RUSSELL, P., "A comparison of Plague vaccine, USP and EV76 vaccine induced protection against <i>Yersinia pestis</i> in a murine model," <i>Vaccine</i> 1995, Vo. 13, No. 16, pp. 1551-1556	
	TABATA, Y. AND IKADA, Y., "Phagocytosis of Polymer Microspheres by Macrophages," <i>Advances in Polymer Science</i> , 1990, Vol. 94, 107-141.	
	VAN ROOIJEN, N., "Antigen Processing and Presentation in Vivo: the Microenvironment as a Crucial Factor," <i>Immunology Today</i> , 1990, Vol. 11, No. 12, pp. 436-439.	
	VIDARD, L., et al., "Analysis of MHC Class II Presentation of Particulate Antigens by B Lymphocytes," <i>Journal of Immunology</i> , 1996, Vol. 156, pp. 2809-2818.	
	WALKER, R., "New Strategies for Using Mucosal Vaccination to Achieve More Effective Immunization," <i>Vaccine</i> , 1994, Vol. 12, No. 5, pp. 387-400.	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
1 Applicant's unique citation designation number (optional)  
2 Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>			
<i>Complete if Known</i>			
<b>Application Number</b>		10/542,449	
<b>Filing Date</b>		December 13, 2005	
<b>First Named Inventor</b>		James Edward Eyles	
<b>Art Unit</b>		1645	
<b>Examiner Name</b>		Swartz, Rodney P.	
Attorney Docket No: 41577/317929			
Sheet	4	of	4

	WILLIAMSON, E, et al., "A sub-unit vaccine elicits IgG in serum, spleen cell cultures and bronchial washings and protects immunized animals against pneumonic plague,' <i>Vaccine</i> , 1997, Vol. 15, No. 10, pp. 1079-1084	
	YAN, C., et al., "Intranasal Stimulation of Long-lasting Immunity Against Aerosol Ricin Challenge with Ricin Toxoid Vaccine Encapsulated in Polymeric Microspheres," <i>Vaccine</i> , 1996, Vol. 14, No. 11, pp. 1031-1038.	
	Abstract of Japanese Patent Publication No. JP 07118170; May 9, 1995	
	Unpublished U.S. Patent Application Serial No. 09,937,066, filed 9-20-2001	
	<b>Response dated 03-02-2009 in related Application No. 10/221954</b>	
	<b>Office Action dated 10-02-2008 in related Application No. 10/221954</b>	
	Unpublished U.S. Patent Application Serial No. 09/937,065, filed 09-20-2001	
	Unpublished U.S. Patent Application Serial No. 09/937,068, filed 09-20-1991	

---

**EXAMINER****DATE CONSIDERED**

---

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached